Department of Health and Human Services
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September 2026 | A-04-23-08095

Medicare Hospital Provider Compliance Audit: McLeod Regional Medical Center

REPORT HIGHLIGHTS

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Why OIG Did This Audit

- For calendar year 2021, Medicare paid hospitals $182 billion, which represented 46 percent of all fee-for-service payments; accordingly, it is important that hospital payments comply with requirements.
- This audit is part of a series of audits examining hospitals with a high volume of claims previously identified as high-risk for noncompliance.
- McLeod Regional Medical Center (the Hospital) was selected because it submitted a substantial number of potentially high-risk claims to Medicare.

What OIG Found

- Of the 115 inpatient and outpatient claims we reviewed totaling $1,516,496, the Hospital complied with Medicare billing requirements for 98 claims. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 17 claims, resulting in net overpayments of $38,676 from January 1, 2020, though December 31, 2021 (audit period).
- These errors occurred primarily because the Hospital did not always follow its policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

What OIG Recommends

We recommend that the Hospital refund to the Federal government $38,676 in net overpayments, consider conducting internal audits for claims after our audit period based on the risks identified by this audit, and provide additional training regarding Medicare billing requirements. Our complete recommendations are found in the audit report.

The Hospital agreed with most of our findings but did not provide concurrence or nonconcurrence with our recommendations. The Hospital stated it will refund the agreed upon net overpayments and described actions it implemented to address our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

For calendar year 2021, Medicare paid hospitals $182 billion, which represented 46 percent of all fee-for-service payments. This audit is part of a series of hospital compliance audits. Previous Office of Inspector General (OIG) audits at other hospitals identified certain types of inpatient and outpatient hospital claims as being at risk for noncompliance.[1] Using computer matching, data mining, and other data analysis techniques, we identified hospitals with a disproportionate number of these claims. We selected McLeod Regional Medical Center (the Hospital) for this audit because it was one of those hospitals that had a substantial number of claims submitted to Medicare in areas OIG designated as high-risk.[2]

OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims from January 1, 2020, through December 31, 2021 (audit period).[3]

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for enrollees after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. CMS uses Medicare Administrative Contractors (MACs) to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

Under the inpatient prospective payment system (PPS), CMS pays hospital costs at predetermined rates for enrollee discharges. The rates vary according to the diagnosis-related group (DRG) to which an enrollee's stay is assigned and the severity level of the enrollee's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the enrollee's stay. In addition to the basic

[1] Hospital compliance audit reports issued by OIG are published on the OIG website.

[2] Submitting claims at risk for noncompliance does not by itself mean the claims were noncompliant. Determinations of noncompliance are completed by independent medical review.

[3] This was the most recent data available at the time we started this audit.

prospective payment, hospitals may be eligible for an additional payment, called an outlier payment, when the hospital's costs exceed certain thresholds.

Hospital Outpatient Prospective Payment System

Under the hospital outpatient PPS, Medicare pays for hospital outpatient services on a per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.[4] All services and items within an APC group are comparable clinically and require similar resources. The HCPCS includes the American Medical Association's (AMA's) Current Procedural Terminology (CPT®)[5, 6] codes for physician services and CMS-developed codes for certain nonphysician services.[7]

Hospital Claims at Risk for Incorrect Billing

We reviewed the following OIG-designated high-risk areas as part of this audit:

- Inpatient claims with the following:
    - Comprehensive error rate testing (CERT) error-prone DRG codes[8]
    - High-severity level DRG codes
    - DRGs for severe malnutrition

[4] The healthcare industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

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[7] 45 CFR § 162.1002(c)(1); *The Medicare Claims Processing Manual*, Publication No. 100-04 (the *Manual*), chapter 4, § 20.1.

[8] CMS calculates the Medicare Fee-for-Service improper payment rate through the CERT program. Each year, CERT evaluates a statistically valid stratified random sample of claims to determine whether they were paid properly under Medicare coverage, coding, and billing rules. As a result of our analysis of CERT data, we identified 10 DRGs that are most at risk for billing errors: 149, 312, 313, 518, 519, 520, 742, 743, 947, and 948.

- Resumption of home health services[9]
- Claims paid in excess of charges
- Mechanical ventilation

- Outpatient claims with the following:
  - Bypass modifiers[10]
  - Claims paid in excess of charges
  - Skilled nursing facility (SNF) consolidated billing claims
  - Magnetic resonance imaging (MRI) claims

For the purposes of this report, we refer to these areas at risk for incorrect billing as "risk areas."

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (Social Security Act (the Act) § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§§ 1815(a) and 1833(e)).

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

Claims must be filed on forms prescribed by CMS in accordance with CMS instructions (42 CFR § 424.32(a)(1)). The *Medicare Claims Processing Manual* (the *Manual*) (chapter 1, section 80.3.2.2) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly.

[9] Resuming home health services means that an enrollee who previously received home health services is starting to receive the services again after a period of hospitalization.

[10] A bypass modifier refers to a two-character code appended to a medical procedure code (CPT or HCPCS) on a claim submitted for reimbursement by Medicare. The modifier serves to override edits that otherwise prevent payment for two or more services billed together.

Limitation on Recovery of Overpayments

MACs may reopen a claim for good cause within 4 years from the date of the initial determination or redetermination.[11] Palmetto GBA, the Hospital's MAC, reopened all claims in our audit sampling frame within 4 years from the date of the initial determination of each of those claims.

Section 1870 of the Act prohibits the recovery of Medicare fee-for-service overpayments if the provider was without fault with respect to the overpayment.[12] A provider is presumed to be without fault for Medicare fee-for-service overpayments if the overpayment determination is made by the Medicare program after the fifth year following the year in which notice of such payment was sent to the provider.[13] MACs typically waive recovery in accordance with this presumption but have the authority to determine whether there is sufficient evidence to rebut the presumption.

McLeod Regional Medical Center

The Hospital is a 547-bed, short-term, acute-care hospital, located in Florence, South Carolina. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately $318 million for 15,713 inpatient and 130,949 outpatient claims during the audit period.

HOW WE CONDUCTED THIS AUDIT

Our audit covered roughly $18 million in Medicare payments made to the Hospital for 3,480 claims in the risk areas identified above.[14] We selected for review a stratified random sample of 115 claims (85 inpatient and 30 outpatient) with Medicare payments totaling about $1.5 million made during our audit period.[15]

We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claim was supported by the medical record. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

[11] 42 CFR § 405.980(b)(2).

[12] Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); *Medicare Financial Management Manual*, chapter 3, §§ 70.3 and 80.

[13] Section 1870; 78 Fed. Reg. 74230, 74445 (Dec. 10, 2013); *Medicare Financial Management Manual*, chapter 3, §§ 70.3 and 80.

[14] The total Medicare payments were $17,712,188.

[15] The total Medicare payments were $1,516,495.

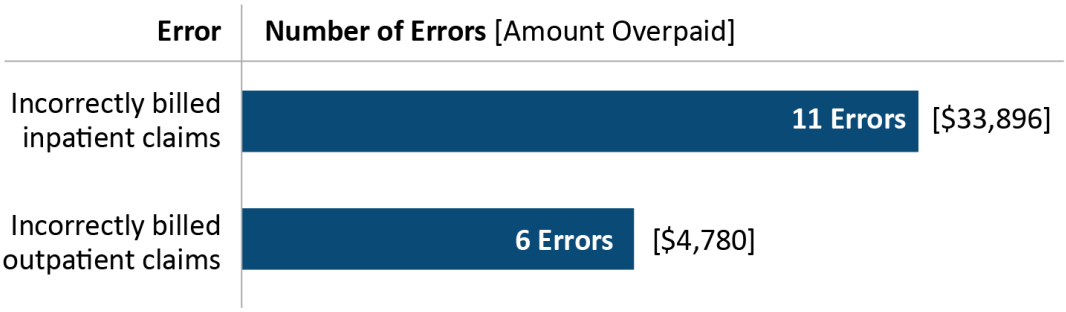
We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 98 of the 115 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 17 claims, resulting in net overpayments of $38,676.[16] Figure 1 provides a breakdown of the error types, number of claims in error and the associated overpayments.

Figure 1: Inpatient and Outpatient Billing Errors



Note: Incorrectly billed inpatient claims include both underpayment and overpayments resulting in net overpayments.

These errors occurred primarily because the Hospital did not always follow its policies and procedures to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

INCORRECTLY BILLED INPATIENT CLAIMS

Diagnosis and Procedure Codes Not Supported

DRG codes are assigned to specific hospital discharges based on claims data submitted by hospitals (42 CFR § 412.60(c)), so claims data must be accurate.

[16] We have chosen not to report any estimates of overpayments in the sampling frame because the lower limit of the two-sided 90-percent confidence interval was less than the known overpayment amount in the sample.

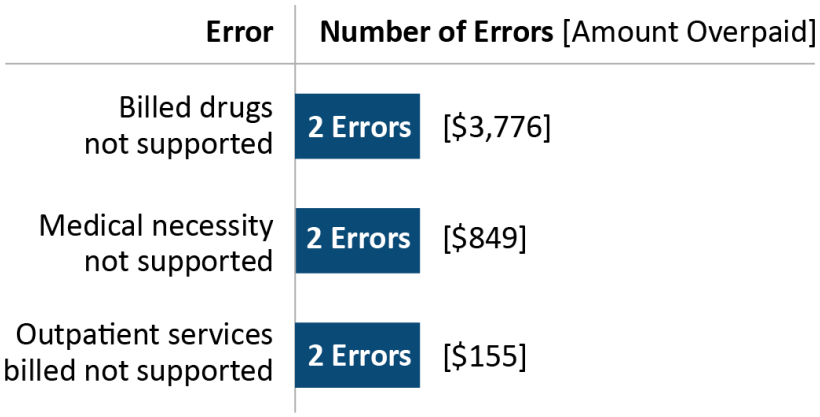
For 11 of the 85 selected inpatient claims, the Hospital submitted claims to Medicare that had diagnosis or procedure codes that were not supported by the medical records, resulting in $33,896 in net overpayments.[17]

Principal Procedure Code Not Supported
One enrollee was admitted in respiratory distress that required intubation with mechanical ventilation. The claim was incorrectly coded with a principal procedure code for respiratory ventilation lasting longer than 96 consecutive hours. However, the enrollee did not receive 96 or more consecutive hours of mechanical ventilation. The change in the principal procedure code caused a change in the DRG code, which should be reimbursed at a lower payment rate.

INCORRECTLY BILLED OUTPATIENT CLAIMS

For 6 of the 30 selected outpatient claims, our independent medical review contractor determined that the Hospital incorrectly billed Medicare Part B for claims that did not meet Medicare criteria for outpatient services.[18] These errors resulted in net overpayments of $4,780. Figure 2 provides a breakdown of the error types, number of claims in error, and the associated overpayments.

Figure 2: Outpatient Billing Errors



[17] Our medical review contractor also determined that 16 of the 85 selected claims did not meet InterQual® Level of Care criteria for inpatient hospital admission. These criteria are evidence-based clinical decision support tools that many hospitals use to help assess clinical appropriateness and strengthen enrollee outcomes. Failure to meet InterQual Level of Care criteria does not equate with failure to meet Medicare requirements, but we believe this is useful information for the Hospital for their quality assurance efforts. See Other Matters for additional information.

[18] Four of the six errors were determined to be in error by our independent medical review contractor and the remaining two were determined to be in error by the Hospital.

Billed Drugs Not Supported

Under the hospital outpatient PPS, Medicare pays for hospital outpatient services on a per-service basis that varies according to the assigned APC (42 CFR § 419.31). CMS uses HCPCS codes and descriptors to identify and group the services within each APC group (42 CFR § 419.2(a)). Federal regulations state that a provider must furnish to the Medicare contractor, sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)). Certain drugs paid under the outpatient PPS are billed using an HCPCS and assigned to an APC. Providers are required to report on their claims for outpatient PPS services the HCPCS for each outpatient service rendered, the date of service, units of service, total charges, and noncovered charges (the *Manual*, chapter 25, section 75.5).

For 2 of the 30 selected outpatient claims, the Hospital incorrectly billed and received payment for outpatient drugs that were provided at no cost to the Hospital. Specifically, the Hospital did not report these drugs as non-covered charges. Overpayments associated with these claims totaled $3,776.

Medical Necessity Not Supported

No payment may be made under Medicare Part B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

For 2 of the 30 selected outpatient claims, the medical record did not include any clinical information supporting the medical necessity of the services billed. Overpayments associated with these claims totaled $849.

Medical Necessity Not Supported
During treatment for non-healing leg ulcers, a procedure for the application of a multi-layer compression system was incorrectly billed. No documentation in the medical record existed to support that these procedures were medically necessary.

Outpatient Services Billed Not Supported

The Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

For 2 of the 30 selected outpatient claims, the medical record did not support that the services billed were rendered. Overpayments associated with these claims totaled $155.

HOSPITAL STAFF DID NOT ALWAYS FOLLOW PROCEDURES TO PROPERLY BILL HOSPITAL SERVICES

The 17 incorrectly billed claims did not comply with Medicare requirements because staff did not consistently follow the Hospital's written policies designed to prevent noncompliance with coding and billing. Although Hospital officials contend that some of the claims met Medicare requirements, they did not provide any additional information that would affect our finding.

RECOMMENDATIONS

- We recommend that the Hospital refund to the Federal government the net overpayments of $38,676 in incorrectly billed claims, excluding amounts presumed to be unrecoverable under the Section 1870 waiver of liability provision.[19, 20]

- We recommend that the Hospital consider conducting one or more internal audits or investigations for claims beyond our audit period, based on the risks identified in this audit, to identify any similar overpayments and return any identified overpayments to the Medicare program.

- We recommend that the Hospital provide additional training to clinical and billing personnel on its policies and procedures related to inpatient and outpatient billing and coding.

HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital agreed with most of our findings but did provide concurrence or nonconcurrence with our recommendations. The Hospital stated it will refund the agreed upon net overpayments and may elect to refund the entire amount of our final net overpayment determinations after considering the time and effort of appeal. The Hospital described actions it implemented to address the second and third recommendations. Regarding Other Matters, the Hospital stated it does not agree that applying a screening tool would reduce inappropriately billed claims. We summarized the Hospital's comments below.

[19] OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process have five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

[20] Palmetto GBA retains the authority to determine whether there is sufficient evidence to rebut the Section 1870 "fifth year following" "without fault" presumption that might limit the recovery of any of these overpayments.

After reviewing the Hospital's comments, we revised our findings by removing one inpatient claim related to an incorrectly billed diagnosis code and reducing the associated recommended refund amount (from $41,349 to $38,676) for this final report. We maintain that our findings and recommendations, as modified, are valid.

The Hospital's comments are included as Appendix E.

AUDIT RECOMMENDATIONS

Hospital Comments

Regarding our first recommendation, the Hospital stated that it will refund the net overpayments it agreed with and may elect to refund the entire amount after carefully considering the time and effort that would likely be required to appeal the disputed determinations.

Regarding our second recommendation, the Hospital said it investigated and conducted two audits on outpatient claims with no-cost drugs and that no overpayments were identified. The Hospital also engaged with a consultant who conducted individual compliance audits in risk areas that were specified in our audit such as CERT DRGs, mechanical ventilation, payments in excess of charges, and bypass modifiers.

Regarding our third recommendation, the Hospital stated that it consistently provided and will continue to provide training, education and resources for clinical, coding, and billing staff and that it has discussed the errors identified in this audit with relevant staff.

Office of Inspector General Response

We acknowledge and appreciate the Hospital's commitment to timely refunding the agreed upon net overpayments and its consideration of refunding the entire net overpayment identified in this report. In addition, we appreciate that the Hospital has conducted targeted audits and consultant reviews, but we continue to recommend risk-based internal audits beyond the specific audit period to monitor areas where multiple billing and coding errors were identified in our sample. We also appreciate that the Hospital is willing to provide training and staff education.

INCORRECTLY BILLED INPATIENT CLAIMS

Hospital Comments

The Hospital agreed with 6 errors and does not intend to dispute 2 of the 12 inpatient claims determined to have been incorrectly coded and billed. The Hospital stated that the combined net overpayment for these eight claims and the calculated error rate does not reflect aberrant or aggressive coding practices or the need for expanded retrospective reviews. The Hospital

also described workflow revisions it has implemented that are intended to enable coding staff to obtain second-level coding reviews of certain inpatient claims.

The Hospital disagreed with 4 of the 12 inpatient errors. They contended that our medical reviewer erroneously questioned two principal diagnoses and two secondary diagnoses. The Hospital asserted that in each disputed case, the clinical record supported its original coding, citing physician documentation, lab results, progress notes, and CMS/Official Coding Guidelines.

Office of Inspector General Response

We appreciate the Hospital's agreement with six inpatient coding errors and decision not to dispute two errors that produced minor underpayments. We agree that the Hospital's net overpayment and calculated error rate is not evidence of aberrant or aggressive coding, and our report did not assert such a pattern; nor did we suggest expanded retrospective reviews.

After considering the Hospital's comments and reviewing the additional information that the Hospital provided, we decided to remove one sampled claim that was an error in our draft report, because it was correctly coded. We reduced the associated recommended refund amount by $2,673 in this final report. We continue to maintain that the other three coding determinations made by our independent medical reviewers are errors.

INCORRECTLY BILLED OUTPATIENT CLAIMS

Hospital Comments

The Hospital stated that it concurs with the determinations and related overpayments for the two claims where the no-cost drugs were incorrectly billed. The Hospital notes that two audits were conducted, one that looked at all no-cost drugs billed to Medicare during the 11-month period of January 1 – November 30, 2022. The second audit reviewed the drug paliperidone.[21] In addition, the Hospital concurred with the determinations and net overpayments for the two claims where the outpatient services were not supported as billed. The Hospital does not believe these errors warrant corrective action or additional focused reviews and indicated a new wound care clinic electronic health records (EHRs) system has alleviated the issue of missing wound care clinic records.

The Hospital did not agree with the remaining two outpatient claim errors. Both errors involved several wound care clinic encounters for the removal and re-application of compression systems (Duke Boots) for which documentation was missing that the Hospital stated was provided to us after we made them aware of the errors.[22] In addition, the Hospital

[21] Paliperidone is a drug used alone or with other mood medicines to manage a mix of psychotic symptoms and mood problems like depression or mania.

[22] A Duke Boot is a type of multi-layer compression wrap used in wound care, particularly for treating leg ulcers.

stated that it subsequently provided clinic notes that support that fully support that the bilateral services were performed. The Hospital questioned whether our medical review contractor received or reviewed these additional records, or why these claims were questioned if the records were received and reviewed.

Additionally, for each date of service in both errors, the Hospital requested that we also consider the impact of underpayments resulting from missing modifier 50, noting that all encounters were bilateral and should have been coded accordingly.[23]

Office of Inspector General Response

We appreciate the Hospital's concurrence with four of the six outpatient errors. We commend the Hospital's decision to implement a new EHRs system for its wound care clinic to ensure the completeness of its medical records.

Regarding the two disputed errors, we disagree with the Hospital's claims that the additional documentation submitted supports the wound-care services or that the medical review contractor failed to receive or review those materials. After evaluating both the original and supplemental records, our independent medical reviewers found that several dates of service lacked adequate documentation of wound evaluation, rendering those services not medically necessary. In both errors, our medical reviewers determined that although some dates were properly supported, the disputed encounters were documented only with discharge instructions or treatment lists rather than clinical assessments needed to justify reapplication of bilateral Duke Boots. Because the unsupported dates of service did not meet medical necessity requirements, we affirm the medical reviewer's original determinations and therefore, did not consider modifier 50 or any underpayment adjustments.

CLAIMS ASSOCIATED WITH INTERQUAL® LEVEL OF CARE CRITERIA

Hospital Comments

The Hospital stated that it was somewhat confused with the implication that using a screening tool would have reduced billing errors, noting that all 85 inpatient claims met the Two-Midnight Rule and were properly billed, and that CMS does not require a commercial screening tool for Part A payment. In addition, the Hospital stated that although two admissions that did not meet InterQual® criteria were miscoded, they were multi-day hospitalizations that met the Two-Midnight Rule, and the Hospital fails to see how the application of InterQual® would have benefited their compliance or utilization review programs.

[23] Modifier 50 is used to report that an identical procedure or service was performed on both sides of the body during the same operative session by the same physician.

Office of Inspector General Response

We agree that the 85 inpatient claims met the Two-Midnight Rule, despite some of the claims not meeting InterQual® criteria, and we did not report these claims as errors. We do not contend that CMS requires a commercial screening tool. However, we believe that the use of such a tool can increase the strength of the Hospital's internal controls that are part of its compliance program.

OTHER MATTERS

Claims Associated With InterQual Level of Care Criteria

During our audit period, CMS required its medical review contractors to use a screening tool as part of their medical review of acute inpatient PPS claims (*Medicare Program Integrity Manual* (*MPIM*), chapter 6, § 6.5.1). CMS did not require that the contractor use a specific tool, nor does CMS or the OIG endorse any specific tool.[24] During an earlier series of hospital compliance audits, in response to findings that claims did not meet Medicare inpatient admission requirements, several auditees noted that their documentation supported that the claims met the InterQual® or MCG Care Guidelines (the successor to Milliman Care Guidelines) screening tools.[25]

As part of this audit, we asked our independent medical review contractor to apply clinical screening criteria to review the Hospital's inpatient PPS claims. This was done for informational purposes to provide the auditee with additional information that might assist them with their compliance and utilization review programs.

The contractor used InterQual® criteria to evaluate a sample of 85 claims. For 16 of those claims, our independent medical review contractor found that the admissions did not meet InterQual® criteria. Although those claims do not constitute a failure to meet Medicare requirements, the results of our audit suggest that properly applying a screening tool in the Hospital's compliance or utilization review programs would reduce inappropriately billed claims.

[24] Several commercially available screening tools exist, including InterQual® Level of Care Criteria, MCG Care Guidelines Inpatient & Surgical Care Guidelines, and other proprietary systems.

[25] For example, see *Medicare Hospital Provider Compliance Audit: Lake Hospital System* (A-05-19-00024), June 30, 2021, and *Medicare Hospital Provider Compliance Audit: St. Vincent Hospital* (A-05-18-00040), Nov. 27, 2019.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $17,712,188 in Medicare payments to the Hospital for 3,480 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 115 claims (85 inpatient and 30 outpatient) with payments totaling $1,516,495.[26] Medicare paid these 115 claims from January 1, 2020, through December 31, 2021 (audit period).

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and submitted all claims to an independent medical review contractor to determine whether the claims were supported by the medical records.

This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

During our audit, we did not assess the overall internal control structure of the Hospital. Rather, we limited our review to the Hospital's internal controls for compliance with Medicare billing requirements. To evaluate these internal controls, we:

- Interviewed Hospital officials regarding the Hospital's internal controls for compliance with Medicare billing requirements that related to the risk areas we identified

- Obtained an understanding of the Hospital's policies and procedures related to the medical necessity of inpatient and outpatient services, the billing of services provided, inpatient and outpatient coding, and the Two-Midnight Rule by reviewing an internal control questionnaire.

- Reviewed a stratified random sample of 85 inpatient claims and 30 outpatient claims to determine if claims were properly billed and reimbursed

- Discussed with Hospital officials the cause of the identified errors

METHODOLOGY

We took the following steps to accomplish our objective:

[26] For claim selection, CMS instructs Medicare review contractors to apply the "Two-Midnight Presumption" and avoid reviewing stays spanning 2 or more midnights, unless there is evidence of systemic abuse, gaming, or care delays (*MPIM*, chapter 6, § 6.5.2). The Two-Midnight Presumption is CMS guidance directing Medicare reviewers to presume that an inpatient admission is appropriate and medically necessary when an enrollee remains in the hospital for at least two midnights after a physician orders inpatient status unless there is evidence of systemic abuse, gaming, or care delays. However, OIG is not constrained by the Two-Midnight Presumption for the purpose of selecting claims for review.

- Reviewed applicable Federal laws, regulations, and guidance
- Extracted the Hospital's inpatient and outpatient paid claims data from CMS's NCH database for the audit period
- Used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements
- Created a sampling frame of paid Medicare claims from selected risk areas consisting of 3,480 claims with a total paid amount of $17,712,188
- Selected a stratified random sample of 115 claims (85 inpatient and 30 outpatient) with payments totaling $1,516,495
- Reviewed data from the Recovery Audit Contractor Data Warehouse for the claims included in the sample to determine whether the claims had been previously reviewed
- Obtained from the Hospital all supporting documentation for the claims in our sample
- Used an independent medical review contractor to determine whether all claims complied with selected billing requirements
- Calculated the correct payment for those claims requiring adjustments
- Discussed the results with Hospital officials

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame contained 3,480 Medicare paid claims in 10 risk areas totaling $17,712,188 from which we selected our sample (Table 1). The sampling frame included claims:

- With only certain discharge status and diagnosis codes
- With payments greater than $0
- Not under review by the Recovery Audit Contractor as of October 21, 2022

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Claims Billed with High CERT Error DRG Codes, Inpatient Claims Billed with High-Severity Level DRG Codes, Inpatient Claims Billed with Severe Malnutrition, Inpatient Claims Billed for Resuming Home Health, Inpatient Claims Paid In Excess of Billed Charges, Inpatient Claims Billed with Mechanical Ventilation, Outpatient Claims Billed with Bypass Modifiers, Outpatient Claims Paid in Excess of Billed Charges, Outpatient Claims Billed for SNF Consolidated Billing, and Outpatient Claims Billed for MRIs.

Table 1: Risk Areas

Medicare Risk Area	Frame Size	Value of Frame
1. Inpatient Claims Billed with High CERT Error DRG Codes	328	$2,788,918
2. Inpatient Claims Billed with High-Severity Level DRG Codes	890	8,558,990
3. Inpatient Claims Billed with Severe Malnutrition	136	3,417,411
4. Inpatient Claims Billed for Resuming Home Health	49	607,317
5. Inpatient Claims Paid in Excess of Billed Charges	13	132,399
6. Inpatient Claims Billed for Mechanical Ventilation	29	1,081,643
7. Outpatient Claims Billed with Bypass Modifiers	116	453,356
8. Outpatient Claims Paid in Excess of Billed Charges	42	148,518
9. Outpatient Claims Billed for SNF Consolidated Billing	13	1,863
10. Outpatient Claims Billed for MRIs	1,864	521,773
Total	**3,480**	**$17,712,188**

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We grouped the sampling frame into strata based on risk areas in Table 1 and claim paid amount, resulting in four strata. Strata 1 and 2 include claims from inpatient risk areas 1 through 6, separated by paid amount;[27] stratum 3 includes claims from outpatient risk areas 7 through 9; and stratum 4 includes outpatient claims from risk area 10. All claims were unduplicated, appearing in only one risk area and only once in the entire sampling frame.

We selected 115 claims for review as shown in Table 2.

Table 2: Claims by Stratum

Stratum	Claims Type	Frame Size (Claims)	Value of Frame	Sample Size
1	Inpatient Risk Areas 1–6, Low Dollar Claims	1,219	$10,008,175	43
2	Inpatient Risk Areas 1–6, High Dollar Claims	226	6,578,504	42
3	Outpatient Risk Areas 7–9	171	603,737	15
4	Outpatient Risk Area 10	1,864	521,773	15
	Total	**3,480**	**$17,712,188***	**115**

* Total is off $1 due to rounding of amount in each stratum.

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services (OIG/OAS) statistical software.

METHOD FOR SELECTING SAMPLE UNITS

We sorted the items in each stratum by a unique claim identifier, and then consecutively numbered the items in strata 1, 2, 3, and 4. After generating the random numbers in accordance with our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We have chosen not to report any estimates of overpayments in the sampling frame because the lower limit of the two-sided 90-percent confidence interval was less than the known overpayment amount in the sample. Therefore, we are recommending recovery of the actual overpayments in the sample.

[27] Paid claims less than or equal to $15,033 are in stratum 1, and paid claims greater than $15,033 are in stratum 2.

APPENDIX C: SAMPLE RESULTS

Table 3: Sample Details and Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Net Overpayments in Sample
1	1,219	$10,008,175	43	$349,403	4	$(1,187)
2	226	6,578,504	42	1,103,327	7	35,083
3	171	603,737	15	60,678	6	4,780
4	1,864	521,773	15	3,088	-	-
Total	**3,480**	**$17,712,188***	**115**	**$1,516,495***	**17**	**$38,676**

* Total is off $1 due to rounding of amount in each stratum.

APPENDIX D: RESULTS OF AUDIT BY RISK AREA

Table 4: Sample Results by Risk Area*

Risk Area	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Net Overpayments in Sample
Inpatient Billed with High CERT Error DRG Codes	17	$193,565	-	$-
Inpatient Billed with High-Severity Level DRG Codes	44	566,293	5	17,749
Inpatient Severe Malnutrition	15	407,011	2	(9,859)
Inpatient for Resuming Home Health Services	2	21,685	1	(2,047)
Inpatient Paid in Excess of Charges	-	-	-	-
Inpatient Billed with Mechanical Ventilation	7	264,175	3	28,053
Inpatient Totals	**85**	**$1,452,729**	**11**	**$33,896**
Outpatient With Bypass Modifiers	8	$26,327	2	$849
Outpatient Paid in Excess of Charges	6	34,266	3	3,846
Outpatient SNF Consolidated Billing	1	85	1	85
Outpatient Claims Billed with MRIs	15	3,088	-	-
Outpatient Totals	**30**	**$63,766**	**6**	**$4,780**
Inpatient and Outpatient Totals	**115**	**$1,516,495**	**17**	**$38,676**

* The table above illustrates the results of our audit by risk area. We organized inpatient and outpatient claims by the risk areas we reviewed. However, we organized this report's findings by the types of billing errors we found. Because the information is organized differently, the information in the individual risk areas in this table does not precisely match the information in the Findings section of this report.

McLeod Health

The Choice for Medical Excellence

May 22, 2026

VIA ELECTRONIC MAIL

Truman M. Mayfield
Regional Inspector General for Audit Services
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

RE: Report Number A-04-23-08095
Medicare Hospital Provider Compliance Audit: McLeod Regional Medical Center

Dear Mr. Mayfield:

Thank you for providing a draft of the OIG's audit report, and for giving us the opportunity to respond regarding the preliminary audit findings and recommendations. I also want to take this opportunity to thank you and your staff for the collegial and professional manner in which this audit was conducted. Although the audit took considerably longer than either of us likely anticipated, we are quite pleased with the outcome and appreciate the opportunity to have demonstrated the organization's commitment to compliance; the proficiency of our clinical, coding, and billing staff; and the accuracy of the hospital's Medicare billings.

Our written comments regarding the OIG's draft findings and recommendations are reported below in the order in which they are referenced in the report, beginning on page 5.

Incorrectly Billed Inpatient Claims

Diagnosis and Procedure Codes Not Supported

We agree with and/or do not intend to dispute the audit findings for eight of the twelve inpatient claims which were determined to have been coded and billed incorrectly, as further described below:

- Three of the coding errors (for samples #34, #53, and #75) were previously identified in our self-audit, which was provided to the OIG in advance of the medical contractor's review;

- Three other coding errors (for samples #30, #47, and #51) were subsequently agreed upon when we were first informed of the medical review contractor's initial determinations, and were asked to provide written responses via the OIG's internal control questionnaire (ICQ); and

- Although we are not in agreement with the coding errors identified for two samples (#17 and #44), we are not going to dispute the medical review contractor's determinations since both alleged errors resulted in relatively minor underpayments from Medicare.

The combined net overpayment for all eight of the agreed upon or non-disputed claims is $125.51, which equates to an error rate of 0.01%. In our opinion, this error rate is not reflective of a pattern or trend of aberrant or aggressive coding practices, nor is it indicative of the need for an additional, expanded retrospective review. However, we did inform the applicable HIM staff of the specific coding errors identified for these eight cases, and we will continue to provide all the hospital's coding staff with proper instruction, training, and up-to-date coding references. We have also revised our practices and workflows to enable our inpatient coders to obtain a second, confirmatory coding review of inpatient cases involving ventilation management services with a duration approximating 24 or 96 hours; a single secondary MCC diagnosis, an admission following an outpatient surgical procedure; and the admission of complex patients transferred from an outside hospital. Also, following the submission of our self-audit findings to the OIG, we engaged a consultant to conduct a number of compliance reviews encompassing most of the risk areas identified by the OIG, including the various DRGs identified in the two inpatient strata within the OIG audit sample. These reviews are further described below, in conjunction with our response to the OIG recommendations:

We do not concur with the audit findings for the other four sample items for the reasons noted below:

- Sample item #13 - we are not in agreement with the medical review contractor's determination relative to a principal diagnosis of COPD exacerbation for this inpatient encounter. While we acknowledge the patient's COPD may have precipitated her acute respiratory failure, we are of the opinion that the reason for the patient's admission, after study, was acute hypoxic, hypercapnic respiratory failure, as documented at the time of her admission to the CCU, and as evidenced by her concurrent arterial blood gas results (with an elevated partial pressure of CO_2), and her worsening hypoxia (requiring CPAP). Thus, we continue to believe this sample item was coded and billed correctly and reimbursed appropriately by Medicare.

- Sample item #21 - we continue to believe the secondary MCC diagnosis of acute post-hemorrhagic anemia was coded correctly (contrary to the medical review contractor's determination). This diagnosis was substantiated in a progress note two days after the surgical repair of the patient's hip fracture and was subsequently confirmed by the treating physician in response to a CDI initiated query one day after discharge. Also, the case summary within the OIG's Review Results document for this sample item includes a reference to the above-mentioned progress note, and states "...the anemia was thought to be due to postoperative acute blood loss ..." Thus, we are not in agreement with the medical review contractor's finding and calculated net overpayment for this sample item.

- Sample item #68 - we do not agree with the medical review contractor's determination regarding the resequencing of cardiac arrest as the principal diagnosis for this inpatient encounter. While we acknowledge the patient experienced cardiac arrest of an apparent non-cardiac cause prior to arrival, requiring resuscitation by EMS and in the ED, lab studies revealed a markedly elevated CO_2 level with a low pH, indicating severe acute respiratory acidosis. She was subsequently admitted with acute hypercapnic respiratory failure (which was also the first listed diagnosis on her post-expiration discharge summary). Thus, we continue to believe that this encounter was coded, billed, and reimbursed appropriately.

- Sample item #80 - we continue to believe that the secondary MCC diagnosis of COVID-19 was coded correctly due to the patient having a lab test positive for COVID-19. This is evidenced in the OIG's Review Results case summary, which states "COVID-19 screening resulted positive (p 95)." According to Official Coding Guidelines in effect at the time of this encounter (2021), asymptomatic patients who test positive for COVID-19 are considered to have COVID-19 infection. Furthermore, various CMS directives during the Public Health Emergency stipulated that a positive COVID-19 lab test (performed during or within 14 days of a hospital admission) was required to substantiate a diagnosis code assignment of U07.1, irrespective of a patient's symptoms or treatment. Thus, we are of the opinion that the Medicare review contractor's determination is in error, and that this sample item was coded and billed correctly and appropriately reimbursed by Medicare.

We do not anticipate initiating any alternative corrective actions in response to the OIG's audit findings for the four cases described above, although the remedial measures discussed previously are intended to facilitate the continued accuracy of the code assignments and claim submissions for all the hospital's inpatient encounters.

Incorrectly Billed Outpatient Claims

Billed Drugs Not Supported

We concur with the audit determinations and resulting overpayments for both outpatient claims for which the reimbursed drugs were billed incorrectly (sample items #97 and #98). As noted in footnote 18 of the report, we informed the OIG of these errors, initially with the submission of our self-audit findings, and again after we were informed of the medical review contractor's initial audit determinations and were asked to provide responses via OIG's ICQ. Upon discovery of these two errors (both of which involved an injectable drug, paliperidone, which was obtained at no-cost from the manufacturer), the hospital initiated two separate audits, the first of which encompassed all outpatient claims on which a no-cost drug was billed to Medicare during the 11-month period (Jan 1 – Nov 30, 2022) immediately subsequent to the OIG audit period. This audit failed to reveal any encounters for which paliperidone, or any other no-cost drug was inappropriately reimbursed by Medicare. The second audit, which encompassed the six-year look back period of Jul 1, 2017 - Jun 30, 2023, included all outpatient claims submitted to Medicare with a line-item charge for paliperidone (designated by HCPCS code J2426). This exhaustive review also failed to reveal any other instances in which the hospital was overpaid by Medicare due to the incorrect billing of paliperidone injections obtained at no cost from the manufacturer.

Medical Necessity Not Supported

We do not agree with and, quite frankly, do not understand the medical review contractor's review determination for either of these two sample items (#88 and #89), both of which involve multiple applications of a multi-layer compression system (or "Duke Boot") for non-healing leg ulcers. The outpatient claim for sample item #88 included nine separate encounters at the hospital's wound care clinic during the month of March 2020. All nine encounters involved the removal of previously applied compression systems (necessary to assess and treat the patient's leg ulcers), and the re-application of new compression systems. The medical review contractor initially determined that five of the nine Duke Boot applications were appropriate, and the remaining four could not be substantiated by the requisite supporting documentation. Upon being informed of these preliminary findings, we realized that our initial document submission to the OIG inadvertently did not include the wound care clinic notes for the four "denied" dates of service, which we subsequently provided with our ICQ responses.

All four of the "previously missing" wound care clinic notes substantiated the re-application of bilateral Duke Boots for all four applicable dates of service. Since the medical review contractor's preliminary findings remain unchanged for these four dates of service, we suspect the contractor either did not receive, or perhaps overlooked, the additional documentation we provided. Also, we do not understand the rationale for characterizing the compression system applications as medically unnecessary for these four dates of service, while the other five applications on this claim were deemed to be medically appropriate. If a compression system is removed to allow for the assessment and treatment of a patient's wounds, it is typically re-applied, unless the wounds have healed or other treatments are initiated.

Sample item #89 is almost identical to the previous sample item, although this claim included ten wound care clinic encounters involving compression system applications during the month of February 2020, five of which were "supported as medically necessary" and were determined by the medical review contractor to be "compliant." The other five compression system applications initially lacked the requisite supporting documentation, which we subsequently submitted to the OIG. Since these previously missing wound care clinic records substantiated the bilateral application of Duke Boots for all five dates of service, we are again questioning whether the medical review contractor received and/or reviewed these additional records. If the contractor did receive and review these records and is now considering the Duke Boots as medically unnecessary, we would appreciate an explanation as to the means of distinction between the five approved, and the five denied compression applications.

In the event the medical review contractor is asked to reassess the determinations for these two sample items, we would again request that the contractor also consider the potential for underbillings resulting from our having mistakenly not appended modifier 50 (designating a bilateral procedure) for five of the compression applications for sample item #88, and for all ten compression applications for sample item #89. (We initially identified the modifier 50 omissions in the self-audit provided to the OIG, and again with the submission of the additional wound care clinic records described above.) As a result of modifier 50 having not been appended to the billed CPT codes for the applicable dates of service on which compression systems were applied to the respective patients' right and left legs, these claims were underpaid by Medicare. Based upon a reimbursement rate of $47.20 for each modifier 50 omission (which equates to 50% of the applicable APC rate of $94.41 for APC 5101), we calculated underpayments of $236.00 for sample item #88 (five incorrectly billed dates of service), and $472.00 for sample item #89 (ten incorrectly billed dates of service). We believe these underpayments should be included in the determination of the overall financial results for this audit.

It should be noted that, subsequent to the OIG's audit period, the hospital implemented a new electronic health record system for the wound care clinic, which will avoid the need to scan various documents into patients' wound care records, and will help to ensure that all pertinent records are included in forthcoming record submissions to outside parties.

Outpatient Services Billed Not Supported

We concur with the medical review contractor's determinations and net overpayment calculations for these two sample items, as both coding/billing errors were initially identified in our self-audit and were subsequently confirmed in our previous ICQ response. The error involving the incorrect assignment of modifier 25 for a family medicine clinic visit appears to be an isolated instance and is likely attributable to an error in judgment on the part of the clinic staff. The other error involves a wound care clinic visit for which we did not provide – and are still unable to locate – the necessary supporting documentation. Neither of these errors, in our opinion, warrants concerted corrective actions or

additional focused reviews, although the new wound care clinic EHR system (discussed above) has alleviated the issue of missing wound care clinic records.

Recommendations

Refund to the Federal Government

We will most assuredly refund the amount of the agreed upon net overpayments shortly after (and well before 60 days after) receipt of notification of the overpayment from Palmetto GBA. After carefully considering the time and effort that would likely be required to appeal the disputed net overpayments and underlying adverse coding/billing determinations, we may elect to refund the entire amount of the OIG's final net overpayment determination.

Internal Audits or Investigations

The only investigation we conducted specifically in response to the OIG audit results involved no-cost drugs provided to Medicare beneficiaries on an outpatient basis. As discussed previously in this response, our investigation encompassed all outpatient Medicare encounters involving any no-cost drug during the first eleven months of 2022, as well as all encounters for which paliperidone (the drug identified in the OIG audit as having been billed and reimbursed in error) was administered to a Medicare outpatient during the six-year lookback period of July 1, 2017 – June 30, 2023. Because this investigation did not reveal additional overpayments from Medicare resulting from the incorrect billing of paliperidone, or any other no-cost drug, we did not extend the investigation beyond June 2023.

As noted previously, we engaged a consultant to conduct several individual compliance audits specifically targeting many of the same risk areas from the OIG audit, as listed below:

- Inpatient claims with CERT DRGs;
- Inpatient claims with high severity level DRGs (including severe malnutrition);
- Inpatient claims with mechanical ventilation DRGs;
- Inpatient and outpatient claims with payments in excess of charges; and
- Outpatient claims with bypass modifiers.

We have also consistently included these same risk areas in the hospital's ongoing compliance audits and compliance monitoring assessments. As is our standard practice, any identified overpayment is refunded to the Medicare program within the required 60-day time frame.

Additional Staff Training

While we have consistently provided, and will continue to provide, our clinical, coding and billing staff with the training, education, and resources (including periodic regulatory pronouncements and revised coding guidelines) necessary to be proficient in the fulfillment of their respective responsibilities, we have found the most effective training occurs by providing the affected staff with the results of governmental, external, and internal audits. Thus, all errors identified in the OIG audit, as well as the discrepancies and improvement opportunities identified in the aforementioned compliance reviews, have been shared and discussed with the responsible staff, as well as, in many instances, other members of their respective departments.

Other Matters

Claims Associated with InterQual® Level of Care Criteria

We are somewhat confused by the OIG's suggestion that "properly applying a screening tool…would reduce inappropriately billed claims," since all 85 of the inpatient sample claims in this audit met CMS' Two-Midnight Rule criteria for an inpatient level of care, and were therefore determined to have been correctly billed to, and appropriately reimbursed by, Medicare as inpatient encounters. Furthermore, CMS has previously stated it is not necessary for a beneficiary to meet an inpatient level of care, as may be defined by a commercial screening tool, for Part A payment to be appropriate.

While we are not aware of all 16 claims for which the medical review contractor determined the admissions did not meet InterQual® criteria, we did note two such claims which were also determined by the contractor to have been coded incorrectly. One (sample item #12) involved a patient who received medically necessary hospital services for six days, and the other (sample item #80) involved a patient whose hospitalization for medically necessary services crossed three midnights. For both cases, we fail to see how the application of InterQual® criteria would have benefited our compliance or utilization review programs.

Mr. Mayfield, thank you again for the opportunity to review and respond to the draft audit report. Please do not hesitate to contact me if any of our responses warrant further clarification, or if additional information or documentation would be helpful in re-evaluating any of the disputed findings.

Sincerely,

Pam Elliott, MHA, BSN, RN, OHCC, CHA
Corporate Chief Compliance Officer

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